UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
NORTHERN DIVISION

JONATHAN GREENWOOD	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No:**
	)	
DAVOL INC.	)	**JURY TRIAL DEMANDED**
	)	
	)	
and	)	
	)	
C.R. BARD INC.	)	
	)	
and	)	
	)	
RED OAK SALES, INC.	)	
	)	
Defendants.	)	

COMPLAINT

For Jonathan Greenwood's cause of action against all Defendants, it is alleged as follows:

PARTIES AND JURISDICTION.

1. Plaintiff, Jonathan Greenwood, resides and is domiciled in Linn County, Missouri and is Missouri citizen.

2. Defendant C.R. Bard, Inc. ("Bard") is a foreign corporation with its principal office and place of business at 730 Central Avenue, New Providence, New Jersey 07974. At all times relevant herein, Bard was doing business in the State of Missouri and designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be permanently and surgically

implanted in patients throughout the United States.

3. Defendant Davol Inc. ("Davol") is a foreign corporation with its principal place of business at 100 Crossing Boulevard, Warwick, Rhode Island 02886, and is a wholly owned subsidiary of Bard. At all times relevant herein, Davol was doing business in the State of Missouri and designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States.

4. Defendant Red Oak Sales, Inc. ("Red Oak") is incorporated and has its principal place of business in North Carolina and is a wholly owned subsidiary of Bard. Red Oak supplied polypropylene resin to Bard and/or Davol to make the mesh. The polypropylene Red Oak purchased was knowingly provided by Red Oak to Bard/Davol for use in meshes sold in Missouri and throughout the Unities States.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interests and costs.

6. Venue is proper under 28 USC §1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred where the Plaintiff was injured in 2016, and where he resides, in Linn County Missouri, in the Northern Division of the Eastern District of Missouri. It is also proper under 28 USC §1391 (c)(2) in that Defendants are subject to the Court's personal jurisdiction because of substantial and continuous contacts within this District sufficient to subject it to personal jurisdiction, consisting of medical device sales and marketing on a substantial scale. Divisional

venue is proper under Local Rule 3-207 because Defendants are corporations without principal places of business in Missouri but who do business throughout the Eastern District of Missouri and within the Northern Division.

FACTUAL ALLEGATIONS

7. This action is brought within 5 years of Plaintiff's awareness of the mesh plug as the cause of his pain, which occurred on or around 6/13/16 when the mesh was removed, and is within 5 years of the accrual of his cause of action within the meaning of RSMO §516.100 and §516.120(4) and *Elmore v. Owens-Illinois, Inc*, 673 SW2d 434, 436 (Mo. banc 1984).

8. Defendants Bard and Davol design, manufacture, market, package, label and sell medical devices, including The PerFix Plug hernia repair medical device, one of which was implanted in Plaintiff and which was labeled:

Davol Bard Mesh PerFix Plug,

Extra Large, Monofilament Knitted Polypropylene ,

REF 0112780

LOT 43AND284

(hereinafter "Product"). Defendant Red Oak supplied the polypropylene resin used to make the device. Red Oak was used by Bard and/or Davol to acquire polypropylene resin to make their hernia meshes under the guise that the polypropylene resin would not be used to make medical implants. Red Oak was necessary to acquire the polypropylene resin, because the manufacturers of polypropylene resin knew that Bard was using the polypropylene resin to make permanently implantable medical devices, which is prohibited by the supplier's Material Data Safety Sheet for the polypropylene

resin. Owing to this fact, the manufacturers refused to sell polypropylene resin to Bard, even if Bard indemnified the polypropylene manufacturers. Bard, Davol and Red Oak, acted together to conceal Bard/Davol's relationship and control over Red Oak in order to obtain polypropylene to manufacture their hernia mesh for permanent implantation in the human body in contravention to the MSDS.

9. On or about May 23, 2003, Plaintiff Jonathan Greenwood underwent a surgical hernia repair at Riverside County Regional Medical Center in Moreno Valley, California by Dr. Clifton Reeves, who implanted the Product into Plaintiff's groin.

10. The Product and the mesh used to manufacture the Product, at the time of implantation into Plaintiff, was defective and unreasonably dangerous, in that:

a) The Product and the mesh material degrades and therefore reacts with human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b) The Product and the mesh material harbor infections that adversely affect human tissues and patient health.

c) The Product and the mesh material migrate from the location of their implantation, adversely affecting tissues and patient health.

d) The Product and the mesh material erode into surrounding structures, adversely affecting tissues and patient health.

e) The Product and the mesh material shrinks and/or contracts and hardens, adversely affecting tissues and patient health.

f) The Product and the mesh regularly fail to perform the purpose of

their implantation such that the patient requires additional repair, removal of the device, and/or replacement of the device, all involving repeated treatment and surgery.

g) Due to their various defects, the Product and the mesh regularly cause significant injury to patients such that the Product must be removed, resulting in additional surgery and associated risks, pain, and tissue and nerve damage.

h) The Product and the mesh material provoke a foreign-body response, become embedded in human tissue over time, such that if it needs to be removed due to its various defects, complete removal is difficult or impossible, the removal poses significant risk of damage to organs, nerves and tissues, and results in additional scar tissue, adversely affecting patient health.

i) The Product and the mesh material provoke a foreign-body response that is patient specific and unpredictable, and necessarily involves inflammation. The foreign-body response involves growth and entrapment of nerves and nearby structures into the Product, and inflammation involves and aggravates nerves and nearby structures both grown into and surrounding the Product.

j) The resin used to make the mesh was not meant for medical applications involving permanent implantation in the human body.

k) The Product and the mesh material cause injury resulting in chronic severe debilitating pain.

l) The Product and the mesh material are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body.

m) The risks of the Product and the mesh material do not outweigh the benefits as the risk of recurrence of the hernia is no better than with native tissue repairs and/or other hernia repair procedures.

n) The Product is defective in failing to warn, or failing to warn adequately, of the Product's potential dangers.

o) The Product is neither FDA approved or cleared, and Bard/Davol unreasonably concluded that FDA approval or clearance was not required.

11. Plaintiff was implanted with the Product designed, manufactured, marketed, packaged, labeled, sold, and placed in the stream of commerce by Defendants, and as intended by Defendants. Due to defective and unreasonably dangerous design, failure to warn and/or warn adequately of he Product's potential dangers, defective and unreasonably marketing, and negligence by the Defendants, Plaintiff was required to have an emergency removal of a hard mass containing infected mesh and a perforated appendix, along with another hernia repair, at the University Hospital in Columbia Missouri on 6/11/16, by Dr. Salman Ahmad, and has had further treatment for infection and pain since that time. The Product caused Plaintiff, despite reasonable anticipated use, biological incompatibility and excessive and dangerous inflammation, scarring, and concrete-like mesh-involved masses and other adhesions, resulting in strangulation, entrapment, adherence, destruction, deformation, obliteration and erosion of Plaintiff's appendix, Further, Plaintiff incurred

the pain and inconvenience of two surgeries, and the pain from the mesh entrapping, eroding, adhering and strangulating nearby structures and causing infection in his abdomen. He has incurred incisions, ongoing pain, gait disturbance, medical bills and missed work. These injuries were either caused or aggravated by the defective and unreasonably dangerous nature of the mesh plug as alleged herein.

12. Prior to the time that the Product was implanted into Plaintiff, Defendants were aware of or should have been aware of numerous defects in the Product and the mesh. Despite being aware of the numerous defects and unreasonable risks associated with their product, Defendants manufactured, marketed, and distributed the Product with the intent that it would be implanted in patients. Defendants were aware that implanting the Product in patients was likely to cause injury and harm to some patients into whom the Product was implanted. Defendants also failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients, and failed to use reasonable care in disclosing to doctors the potential adverse consequences of implanting the Product into patients.

13. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Product in patients was safe and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Product and that the Product would be implanted in patients. When Defendants made these statements, Defendants knew or

should have known that the statements were inaccurate.

14. Representatives of Defendants also made statements to numerous individuals, including but not limited to medical professionals, that implanting the Product in patients was safe and would not cause harm to patients. When Defendants' representatives made these statements, Defendants knew or should have known that the statements were inaccurate.

15. Defendants knowingly and deliberately made material misrepresentations or did not disclose information to the United States Food and Drug Administration concerning the design, manufacture, safety, efficacy, and risks of the Product.

16. Before Plaintiff suffered the injuries complained of herein, Defendants were on notice of numerous bodily injuries caused by the Product, and based thereon, Defendants knew or should have known that the Product risks included migration, erosion, infection, perforation, shrinkage and/or contraction, chronic pain, chronic severe debilitating pain, infertility, dysejaculation, degradation, scarring, nerve entrapment, nerve damage, disfigurement, and other complications and injuries including the risks associated with additional removal surgeries in men implanted with the Product.

17. Even though Defendants have known or should have known that the Product created foreseeable, unreasonable risks of harm to those men in whom it was implanted, Defendants continued to market the Product, failed to adequately test and investigate these risks and did not warn or failed to adequately warn of the risks associated with the Product.

18. Defendants have either never warned or provided only inadequate warnings or information of the risks associated with the Product.

COUNT I: NEGLIGENCE

19. Plaintiff repeats and re-alleges the above paragraphs of the Complaint as though fully restated herein.

20. Defendants had a duty to use reasonable care in designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Product for hernia repair. Defendants had a duty to keep abreast of scientific knowledge, discoveries, advances, and medical literature. Defendants had a duty to provide complete disclosure of all risks and the extent of the danger and severity of any potential injury involved with the Product.

21. Defendants were negligent in failing to use reasonable care in designing, manufacturing, testing, packaging, labeling, warning of risks, promoting, distributing and selling the Product for hernia repair. Defendants knew, or should have known, that using the Product created risk of unreasonable and dangerous side effects as well as severe and permanent health consequences. These risks include but are not limited those alleged in paragraph 10.

22. Even after Defendants knew or should have known of the unreasonable, dangerous side effects, as well as other severe and permanent health consequences, Defendants failed to provide warnings, or to provide adequate warnings, and continued to market the Product.

23. Defendants were negligent in failing to warn or instruct Plaintiff and/or his health care providers of the risks and the extent of the danger and severity of

potential injuries involved with the Product.

24. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in designing, manufacturing, testing, packaging, labeling, promoting, distributing and selling the Product.

25. The conduct of Defendants in continuing to market, sell and distribute the Product after obtaining knowledge that the Product was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum that will serve to deter Defendants from similar conduct in the future.

COUNT II: STRICT PRODUCT LIABILITY

26. Plaintiff repeats and re-alleges the above paragraphs of the Complaint as though fully restated herein.

27. At all relevant times, Defendants together designed, manufactured, tested, packaged, labeled, promoted, distributed and/or sold the Product or the mesh the Product was made of , and Plaintiff was a reasonably foreseeable or intended user or recipient of Defendants' Product. Defendants together exercised significant control over the aforementioned design, manufacture, packaging, or labeling of the Product.

Product Defect
MAI 25.04

28. Defendants sold the Product or the mesh making up the product in the

course of their businesses.

29. At the time of sale, the product or the mesh making up the product was in a defective condition unreasonably dangerous when put to a reasonably anticipated use, as alleged in paragraph 10, and

30. The Product and mesh were used in a manner reasonably anticipated.

31. Such defective condition as existed when the product or the mesh it was made of was sold, caused or substantially contributed to cause the damages alleged in paragraph 11.

Failure to Warn
MAI 25.05

32. Defendants sold the Product or the mesh making up the product in the regular course of their businesses.

33. At the time of sale, the product or the mesh making up the product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, for the reasons alleged in paragraph 10.

34. Defendants failed to adequately warn of the risks alleged in paragraph 10.

35. The Product was used in a manner reasonably anticipated.

36. The Product being sold without an adequate warning, caused or substantially contributed to cause the damages alleged in paragraph 11.

COUNT III: BREACH OF WARRANTY
MAI 25.02 and 25.03

37. The product was sold by Defendants as fit for permanent implantation in the human body and capable of fixing hernia's, but it was not. It failed to function as

advertised and as represented by Defendants because it was not fit for permanent implantation in the human body for the reasons alleged in paragraph 10 and did not relieve the symptoms or otherwise alleviate the medical problems it was intended to cure. In fact, the Product exacerbates and causes additional problems and the need tor additional surgeries. Accordingly, the Product was not fit for the ordinary purpose for which such a good is used and failed to conform to the affirmations or representations of Defendants.

38. Furthermore, Defendants knew that the Product was to be used for the particular purpose for which it was used in Plaintiff and knew the expertise of Defendants was relied upon to furnish suitable goods.

39. The product being unfit for the use for which it was purchased, caused or substantially contributed to cause the damages alleged in paragraph 11.

PUNITIVE DAMAGES MAI 10.05

40. At the time Defendants sold the Peacock and the polypropylene form which it was made, Defendants knew, of the defective and unreasonably dangerous nature of the Product and the polypropylene, and thereby showed complete indifference to, or conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

/s/ Mary Coffey

MARY COFFEY, E.D. Mo # 2837
GENEVIEVE NICHOLS, E.D. Mo #95929
COFFEY & NICHOLS
Attorneys for plaintiffs
6200 Columbia Ave.
St. Louis, MO 63139
Phone: 314-647-0033
Fax: 314-647-8231
E-mail: mc@coffeynichols.com
gn@coffeynichols.com